IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

IN RE: TRICOR DIRECT PURCHASER ANTITRUST LITIGATION	)	C.A. No. 05-340 (KAJ)
	)	Hon. Kent Jordan, U.S.D.J.
THIS DOCUMENT RELATES TO: ALL ACTIONS C.A. Nos. 05-340, 05-404, 05-605 (KAJ)	)	

COMPENDIUM OF UNREPORTED CASES AND OTHER AUTHORITIES IN SUPPORT OF DIRECT PURCHASER PLAINTIFFS' ANSWERING BRIEF IN OPPOSITION TO DEFENDANTS' CONSOLIDATED MOTION TO DISMISS

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December 2, 2005

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TAB

TAB 1

DRUG PRODUCT SELECTION

Staff Report to the

Federal Trade Commission

BUREAU OF CONSUMER PROTECTION

JANUARY 1979

[redacted]

DRUG PRODUCT SELECTION

Staff Report to the Federal Trade Commission

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JANUARY 1979

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DRUG PRODUCT SELECTION

Staff Report to the Federal Trade Commission

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SUMMARY OF CONTENTS

CHAPTER I. INTRODUCTION

On July 7, 1976, the Federal Trade Commission opened an investigation into the sale of multisource prescription drugs.[1] Staff of the Bureau of Consumer Protection submits this report on whether price competition for multisource prescription drugs is unduly restricted by state antisubstitution laws that prohibit pharmacists from selecting lower-cost sources of drugs prescribed by brand name, and whether the Commission should attempt to remedy any existing problem. We have completed our investigation[2] and have concluded that antisubstitution laws impose substantial unwarranted costs on consumers[3] by unduly restricting price competition in the multisource prescription drug market.[4] We further conclude that the repeal of antisubstitution laws would produce significant consumer benefits without compromising the quality of health care.[5] To remedy the situation and facilitate pharmacists' selection (also called "substitution" or "brand

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1 Resolution Directing Use of Compulsory Process in Nonpublic Investigation, File No. 762-3124, July 7, 1976.

2 During the course of our investigation we sought comments and documentation from, inter alia, the major brand-name drug manufacturers; brand-name and generic manufacturers' associations; pharmacy and medical associations; the drug wholesalers' association; the Deans of each of the nation's colleges of pharmacy; and from consumer groups. We further obtained information from the academic community, including experts in biopharmaceutics; state pharmaceutical boards, associations and formulary commissions; other federal agencies, including the Food and Drug Administration; business organizations; and from individual pharmacists, physicians and consumers. We hired four economic consultants, representing a range of views, to provide their assessments of the potential impact of drug product selection on manufacturers' research and development incentives (see Ch. IX.A., infra). And in addition to collecting existing studies, we hired an independent market research firm to conduct a multistate survey of pharmacists' attitudes toward their state's drug product selection law (see Ch. VII.C.3., infra).

3 See discussion of potential consumer benefits in Ch. VIII., infra.

4 See discussion of the role of antisubstitution laws in insulating brand-name manufacturers from price competition, Ch. II.D., infra.

5 See analysis of alleged disadvantages of drug product selection at Ch. IX., infra.

interchange") of drug products therapeutically equivalent to but less expensive than products prescribed by brand name, we recommend that the states adopt the Model Drug Product Selection Act discussed in Ch. X.A., infra.[6]

A. The Problem

Prescription drugs, which seldom are covered by insurance plans, cost American consumers over eight billion dollars in 1977.[7] Persons over age 65, who comprise 11 percent of the population, pay 25 percent of the national drug bill, and often must do so on limited fixed incomes.[8] A considerable portion of this expenditure could be saved if the market fostered the purchase of low-cost equivalent drug products.

The basic problem is that the forces of competition do not work well in a market where the consumer who pays does not choose, and the physician who chooses does not pay. Patients

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6 This Report generally adopts the term "drug product selection" rather than "brand interchange" or "substitution." "Brand interchange" may mistakenly imply that the pharmacist is limited to selecting another branded drug product for the one prescribed, rather than an unbranded product. "Substitution" may mistakenly imply that the pharmacist is allowed to select an entirely different drug entity for the one prescribed, rather than merely a different manufacturer's formulation of the same drug, or to do so surreptitiously. (In fact, as documented in Ch. VII.A., infra, antisubstitution laws developed at a time when substitution generally did refer to deceptively dispensing a different drug entity.) "Drug" is used in this Report to indicate the active chemical ingredient or drug entity. "Drug product" means a particular manufacturer's formulation of that same drug entity. Thus, for example, "Miltown" and "Equanil" are two drug products distributed by Wallace Laboratories and Wyeth Laboratories respectively, each containing the identical drug--meprobamate. Meprobamate also may be prescribed alone or in combination under the following brand names, among others: Meprospan, Meprotabs, SK-Bamate, Tamate, Appetrol, Bamadex, Cyclex, Deprol, Equalysen, and Pathibamate. USAN and the USP Dictionary of Drug Names (M.C. Griffiths ed. 1976), at 172-173.

7 Pharmacy Times, April 1978, at 41, 48. See Ch. V.A., infra, for a discussion of drug costs.

8 Drug Topics, Sept. 1, 1977. See discussion of the special problems of the elderly at Ch. V.B., infra.

have little influence in determining which products they will buy and what prices they must pay for prescriptions.

Chemically (and therapeutically) equivalent versions of "multisource" prescription drugs (drugs available from more than one manufacturer) are frequently sold at widely disparate prices. For example, ampicillin trihydrate, a commonly-prescribed antibiotic, is available at wholesale prices ranging from $18.74 to $6.00 per hundred capsules.[9] This wide price disparity is evidence of the low priority placed on drug prices by prescribing physicians. In fact, most physicians have little knowledge of drug prices. One recent study[10] asked physicians from a diversity of practices to rank their knowledge of drug prices on a scale from one (very informed) to five (uninformed). Of the 144 physicians responding, over 32 percent replied that they had "no idea" of the prices of commonly-prescribed drugs, and over two-thirds of the remainder assessed themselves at a four or five. When the same study measured physicians' knowledge of the prices of drugs prescribed in their specialties, it found that two and a half times as many physicians underestimated as overestimated the price.

The reason for this lack of price awareness is that there is little incentive for physicians to shop around for the least expensive drug products. Patients do not choose their physicians on the basis of the cost of the drugs the physician prescribes. Indeed, probably only a small percentage of patients currently know enough about comparative drug prices or the availability of less expensive generic equivalents to ask physicians to prescribe low-cost drug products.[11] Furthermore, it is time-consuming and therefore costly for physicians to acquire comparative price information. Busy physicians understandably are concerned when choosing drugs primarily with the relative performance, benefits and risks associated with the use of a particular drug. Price considerations necessarily take on a secondary importance, if

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9 See Table 6: "HEW's MAC Savings on Ampicillin Trihydrate 250 mg. caps." in Ch. VIII., infra.

10 Fink & Kerrigan, "Physicians' Knowledge of Drug Prices," 1 Contemp. Pharmacy Prac. 18 (1978). See Ch. III.C., infra, for a discussion of this and similar studies. Except where otherwise indicated, we have not attempted in this Report to analyze the statistical validity of the various surveys cited. Where support is not available from other surveys with consistent findings, we have attempted to indicate that fact or to cite opposing studies.

11 See Ch. VII.B.4 and C.3., infra, for evidence that patients seldom ask pharmacists about the availability of low-cost products.

any at all, at the time the physician decides which drug brand to prescribe.

Drug manufacturers are sensitive to the factors that influence the physician's prescribing decision. They know that they would not gain physician loyalty by having a low price. Instead the manufacturer may do far better by having a memorable brand name.

Many drug products have three names. One is its "chemical name," often understandable only to accomplished organic chemists. An example is the drug sedative with the chemical name 7-Chloro-2-(methylamino)-5-phenyl-3H-1,4-benzodiazepine 4-oxide monohydrochloride. A second name is the "generic" or "established" or "official" name, which is a non-proprietary name used to designate drug products with the same active chemical ingredients. In the previous example, the generic name is chlordiazepoxide hydrochloride. Finally, a "brand" or "trade" name is a designation given to a drug by the manufacturer, which, if registered, can be used exclusively by that company to distinguish its product from other products in the same generic category. In the example, chlordiazepoxide hydrochloride is the active ingredient of Librium, the brand name used by the manufacturer Hoffmann-LaRoche.[12]

Almost 90 percent of all prescriptions are written by brand name.[13] This is partly because brand names are generally shorter and easier to recall than their corresponding generic names. Dr. Solomon Garb, professor of pharmacology at the University of Missouri Medical School, observed:

> I am always amused by the fact that X, Y and Z are rather rare letters in most languages, but when you come to generic names of drugs, I would say about 75 percent of all of them have either an X, Y or Z in them and some of them have all three. Zoxazolamine has two Z's and an X.[14]

And the use of the brand name may obscure the identities of equivalent drug formulations. "Noctec," a brand name used by

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12 USAN and the USP Dictionary of Drug Names, supra note 6, at 61. See discussion of brand names and their promotion by manufacturers in Ch. II.C., infra.

13 Pharmacy Times, supra note 7, at 42.

14 Dr. Solomon Garb quoted in Cong. Research Service, "Competitive Problems in the Drug Industry: Summary and Analysis," Subcommittee on Monopoly, Select Committee on Small Business, U.S. Senate, Nov. 2, 1972, at 44. ["Competitive Problems".]

E.R. Squibb & Sons, "Somonos," a brand name used by Merck Sharp & Dohme, and at least 15 other chemically identical products containing the sedative chloral hydrate (500 milligram capsules) are all made by one manufacturer--the R.P. Scherer Company -- and are sold to pharmacists at prices ranging from $1.48 to $5.00 per hundred.[15]

The total number of drug products in the market is enormous. An HEW Task Force on Prescription Drugs estimated in 1968 that there were about 4,000 different dosage forms of 1,200 single drug entities and about 6,000 combination drug products.[16] The larger drug companies normally assign an individual brand name to each product they sell. During the patent period, when the manufacturer has exclusive production rights, the drug is usually sold under its brand name. During this time, the brand name may become so closely associated with the drug in the minds of physicians that they continue to write it long after expiration of the patent (see discussion of the physician's prescribing decision in Ch. III, infra.) The association of the drug entity with the brand name is fostered by the extensive promotional campaigns of the major drug companies. The core of these campaigns is the company detailer, who makes personal visits to physicians to promote the company's new products. A 1977 FTC Bureau of Economics staff report found that in 1970 thirty of the largest prescription drug manufacturers spent $682 million on drug promotion, an amount representing 21 percent of the firms' total sales in the United States or an expenditure of over $2400 per practicing physician.[17] Faced with this proliferation of heavily-promoted brand names, physicians not surprisingly were found to demonstrate

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15 USAN and the USP Dictionary of Drug Names, supra note 6, at 61; Statement of the American Pharmaceutical Association in "Prescription Drug Labeling and Price Advertising," Hearings on H.R. 882, H.R. 884 and All Identical Bills, Subcommittee on Consumer Protection and Finance, Committee on Interstate and Foreign Commerce, U.S. House of Representatives, 94th Cong., 2d Sess., at 197-198 (1977).

16 HEW Task Force on Prescription Drugs, The Drug Makers and the Drug Distributors 20 (1968). Other estimates are much higher. Dr. James Goddard, former FDA Commissioner, and Dr. Paul Stolley, for example, estimated that there were about 5,000 prescription drugs and 21,000 drug products. Stolley & Goddard, "A 'Relative Efficacy' System for New Drugs," 73 Annals Internal Med. 479-80 (1970), cited in Competitive Problems, id. at n.5.

17 R. Bond & D. Lean, "Bureau of Economics Staff Report to the Federal Trade Commission: Sales, Promotion, and Product Differentiation in Two Prescription Drug Markets," at 1 (1977).

a strong preference for the brands that first entered the market and generally were persuaded to prescribe late-entering brands only if they offered some specific therapeutic gain. The FTC report stated:

> Physicians' preferences for a relatively small number of trademarked, brand-name drugs are probably rational responses to the proliferation of trademarked drugs in the industry as a whole. For just one dosage strength of one generic chemical, 20 mg. PETN, the physician faces a bewildering array of alternatives. In 1971, 61 firms offered PETN, 32 under a brand name. To weigh the quality and price alternatives presented by such an array of drugs would involve a notable feat of research and memory. As one pharmacologist has noted, doctors are human beings, not computers . . .[18]

Brand-name prescribing has a special significance under antisubstitution laws. If the physician writes a prescription for a drug obtainable from different sources by a brand name, neither the pharmacist nor the patient can choose from among diversely priced equivalents. And companies that succeed in familiarizing physicians with their brand-name products therefore are insulated from the competition of lower-priced generic equivalents.

Antisubstitution laws are a relatively recent development (see Ch. VII.A., infra, for a discussion of the history of antisubstitution laws). At the same time the pharmaceutical industry underwent a rapid expansion after World War II, producing sophisticated drugs marketed by brand names, a large number of "counterfeit" drugs appeared on the market.

These counterfeits, resembling the popular brand-name product in color, size, shape and sometimes packaging, but of unknown quality, content and origin, were passed off to consumers through unwitting or unscrupulous pharmacists. Against this background of brand promotion and drug counterfeiting, the National Pharmaceutical Council (an organization of large drug manufacturers) led a highly successful effort to enact antisubstitution laws specifically prohibiting pharmacists from dispensing, not only a different

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18 Id. at 76.

drug entity, but a different brand from the one prescribed.[19]

As new federal controls virtually eliminated drug counterfeiting, states began in the 1960's and 1970's to question the appropriateness of restrictive antisubstitution laws. Within the last five years or so, an ever-accelerating number of states, with major support from consumer groups and pharmacy associations, have replaced their antisubstitution laws with drug product selection laws. These laws, now enacted in 40 states and the District of Columbia (see Table of State Laws and accompanying discussion at Ch. VII.B., infra), permit the pharmacist, unless otherwise directed by the physician or the patient, to select a lower-cost generic equivalent for the brand-name prescribed. The laws recognize that the pharmacist is aware of price differences and can more efficiently select from among competiting products than can physicians. The laws foster price competition by allowing the only principals who have financial incentives to make price comparisons--the pharmacist and the patient--to select drug products on the basis of price.

B. The Issues

In examining antisubstitution laws and deciding whether or not to endorse drug product selection, we considered (and discuss in this Report) several important issues. One group of issues involves drug quality -- the nature and adequacy of FDA's regulation of drug quality, the extent to which drug products with identical active ingredients also provide equivalent therapy, and the question of potential differences between the quality of brand-name and generic-name products (see Ch. VI.A. and Ch. IX.C., infra). Related to these concerns are the pharmacist's technical ability to select drug sources (Ch. IV.A., infra) and the assurance of the physician's right to specify a particular brand when medically necessary (Ch. III. and Ch. IX.B., infra).

A second group of issues involves economic concerns -- the pharmacist's incentives to select low-cost generic equivalents (Ch. II.B., infra) and the extent to which pharmacists actually do choose such products (Ch. VII.C., infra), the potential savings to consumers from drug product selection (Ch. VIII., infra) and the actual savings passed on to consumers by pharmacists (Ch. VII.C., infra). Related to these concerns are the extent to which pharmacists' anxiety about potential liability lawsuits inhibits product selection (Ch. IX.E., infra) and the potential effect of increased selection of low-cost generics on the research and development incentives of brand-name manufacturers (Ch. IX.A., infra).

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19 The role of the National Pharmaceutical Council is discussed at Ch. VII.A.1.c., infra.

absent contrary direction by the doctor, to select a less expensive generic equivalent for the brand-name product prescribed. Antisubstitution laws in themselves, however, may increase the incentive to use product-unique brand names. The important effect that brand-name prescribing can have on a product's sales when its patent has expired makes it less likely that an innovative firm will designate its product by the generic name. Similarly, after the patent expires, antisubstitution laws may increase the incentive for entering drug manufacturers to market their version of the drug using a product-unique brand name. Therefore, antisubstitution laws increase the incentive for innovative and entering firms alike to proliferate the number of brand names. Moreover, as discussed below, antisubstitution laws increase the incentive of manufacturers to promote on the basis of brand names.

2. Antisubstitution Laws Increase the Incentive to Promote

The pharmaceutical industry spends a large portion of its total revenues on brand-name promotion. Athough the figures vary, most estimates run between 20 and 30 percent of the sales dollar.[19] The promotion budget is considerably larger than for research and development, and depending on the figures used, can be a multiple of two to four times as large as the budget for R & D. One large firm, Merck and Co., spent nearly $145,000,000 on R & D for all products in 1977 (based on sales of $1,724,410,000) and $438,000,000 on marketing and administration expenses ($47,000,000 for advertising alone).[20] A recent tabulation published in Advertising Age showed that the top twenty drug firms (according to promotional expenditures) spent nearly $327,000,000 on three forms of promotion (detailing, journal advertising, and direct mailing), of which nearly 70 percent ($222,485,000) was spent on manufacturers' personal representatives, called detailers, who make personal visits to physicians to inform them of their companies'

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19 FTC economists Bond and Lean estimated that in 1970 the thirty largest drug manufacturers spent $682 million on promotion, or 21% of their sales dollar and $2,400 per physician. Bond & Lean, supra note 13, at 1. Other estimates are: 25% for sales expenses including advertising and promotion (Report on Administered Prices of Drugs, Subcommittee on Antitrust and Monopoly, of Senate Comm. on the Judiciary, S. Rep. No. 448, 87th Cong., 1st Sess., 1961, Report 31, at 157); 25% for promotion (Rep. Rosenthal, Cong. Record, Mar. 19, 1973, H. 1884); 35% for marketing: 20% for direct sales, 5% for administration, 10% for advertising and promotion (Hughes, "Prospects for U.S. Health Care Companies, 1975-1977," April 1975, Arthur D. Little, Inc., at 9).

20 Merck and Co., 1977 Annual Report.

Given the significance of brand-name prescribing under antisubstitution laws, however, it is easy to see how these laws encourage huge promotional expenditures: by reinforcing doctors brand-name prescribing habits, drug companies are able to retain their dominant position and continue charging premium prices long after patents have expired.

Most authorities and studies in the area conclude that physicians are less likely than pharmacists to be aware of price differences among multisource drugs. Doctors have numerous responsibilities besides prescribing drugs and appear to be preoccupied with the drug's therapeutic effect when writing a prescription.[25] They use little of their valuable time to learn the availability and price of competing sources of the same drug. And nearly all the information they do receive pertains only to brand-name products.

Antisubstitution laws increase this incentive to promote brand-name drug products. During the patent period, an innovative firm has increased incentive to promote its product's brand name to physicians, hoping that physicians' familiarity with the brand name will lead to widespread prescribing by that name even after the patent expires.

Many analysts see antisubstitution laws operating in a synergistic manner with trademarks, patents, and promotion. During the patent period, the tradename of the drug product often becomes synonymous with the name of the drug entity, at least in the minds of prescribing physicians. Since the trademark never expires, competing firms cannot use that tradename to call attention to their products. This process may effectively extend the patent monopoly past its formal expiration, as is implied in the following passage:

> The patent-holder typically uses the patent period and the revenues it derives from monopoly pricing, to mount a massive promotional

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24 (Footnote Continued)

Journal advertising	10	15
Direct mail	15	70
Sales promotion devices	10	10
Exhibits and conventions	10	------
Other	5	5

Source: FTC Econ. Report on Antibiotics Manufacture, at 129.

25 See Ch. III.C., infra.

> campaign aimed not only at selling the drug under its brand name while the patent lasts but also at linking its name with the product permanently, so that physicians will continue to prescribe the drug by its original brand name long after the patent period has elapsed.[26]

Thus in conjunction with prior patent coverage, heavy promotion campaigns, and state antisubstitution laws, "[t]he value of a trademark may continue long after patent protection has vanished."[27] This interaction is described by the Senate Select Committee on Small Business as follows:

> By promoting and advertising drugs by trade names, manufacturers hope to build loyalty among prescribers who use these products. In States with antisubstitution laws, loyalty to trade-named products is especially important. If the prescriber designates a drug by a trade name assigned to it by a manufacturer, pharmacists must fill the prescription order with the product of the particular supplier, or obtain authority from the physician to use some other versions of the drug available to the pharmacist.[28]

Brand-name promotion, of course, deemphasizes the existence of equivalent products. Antisubstitution laws prevent pharmacists (who are aware of equivalent alternatives) from interchanging lower-cost products for prescriptions written by brand name. Therefore, to the extent that heavy promotion by manufacturers focuses on tradenames, it "reduces the degree of substitutability between products," giving the distributor of brand name products greater latitude in its promotional and pricing behavior.[29]

Moreover, we will see later that in advertising their products to doctors, generic manufacturers face several disadvantages not encountered by the brand-name firms (see Ch. II.D., infra.) Thus, antisubstitution laws may lead to over promotion by brand-name firms attempting to bar the success of lower-priced substitute

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26 Consumer Reports, January 1975, at 51.

27 The Drug Makers, supra note 24, at 41.

28 Cong. Research Service, supra note 6, at 40.

29 Hornbrook, supra note 24, at 29.

is the largest producer of unbranded drug products.[32]

The entry of major firms into the generic market, even though on a somewhat different level, does indicate a brighter future for generics.

d. Promotion of Generic Products

Most generic manufacturers compete primarily on the basis of price.[33] Because they neither engage in original product research nor hold patents, these firms are unable to take advantage of the product differentiation opportunities exploited by brand name manufacturers. There are three major reasons that explain why generic firms engage in little promotion.

First, antisubstitution laws discourage promotion of generic products to pharmacists. For in states where such laws are in effect, there is less opportunity for source selection by the pharmacist. In these states pharmacists can engage in source selection only for generically-written prescriptions. Since the enactment of drug product selection laws, there has been a significant increase in advertising by generic houses.[34]

Second, as indicated earlier, the generic name generally is longer and more difficult to remember than the proprietary name whose rationale is its rememberability. (See Ch. II.C.1., supra). To the extent generic names are more cumbersome than their counter-

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32 Prescription Drug Labeling and Price Advertising: Hearings on H.R. 882, et al., Before the Subcomm. on Consumer Protection and Finance, House Comm. on Interstate and Foreign Commerce, 94th Cong., 2d Sess. 213 (1976):

MANUFACTURERS OF UNBRANDED GENERICS	PERCENT
Eli Lilly	11
Darby	6
Zenith Labs	6
Parke-Davis	6
Generic Corp. of America	5
Purepac	4
Interstate Drug	3
Elkin-Sinn	3
ICN	3
Rachelle Labs	3
All others	50

33 Glennie, supra note 10, at 151.

34 See Millman, "Battle lines harden in fight over generics," Advertising Age, Feb. 13, 1978, at 76.

parts, firms promoting generic drug products find themselves at a relative cost disadvantage compared to the producers of the original drugs. When coupled with the disincentive against promotion created by the ability of competitors to free ride, the complexity of generic names explains why relatively little money is being spent by manufacturers promoting generics.

Third, a generic manufacturer does not have a strong incentive to engage in promotional activities designed to persuade doctors to prescribe generically. In fact, the manufacturer may have a disincentive because its efforts would reward all generic manufacturers of the product, including its "free riding" generic competitors Having persuaded a doctor to prescribe generically, the generic manufacturer would have no assurance that pharmacists who filled the prescription would only dispense its product, particulary if a non-advertising generic manufacturer offered lower prices.

Moreover, even in states where drug product selection laws are in effect, generic firms do not engage in individual product promotion, since the product is not unique from that of rival producers.[35] Instead, both branded-generic and unbranded-generic houses promote lines of products with an emphasis on the name and policy of the producer. Although differences in promotional efforts exist between these two types of generic producers, usually the main target of all generic advertising is the pharmacist who selects the source used to fill generic prescriptions.

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35 Although published data are not available, it appears that the marketing costs for manufacturers of low-cost generic drugs are minimal, and consists mainly of distribution and direct mail advertising expenses. Few such companies engage in substantial medical journal advertising or promotional activities, primarily because product promotion of generically labelled products is illogical. Advertising such a generic name as meprobamate, for example, may popularize the use of the product. But since generically-written prescriptions can be filled with any brand of the product, the small market share of firms selling under generic name means that benefits resulting from their own promotional outlays would probably be uneconomic.

U.S. Dept. of Health, Education and Welfare, Office of the Secretary, Task Force on Prescription Drug, The Drug Makers and the Drug Distributors 20 (1968).

Another important source of drug advertising by brand-name manufacturers is direct mail. Although in recent years direct mail expenditures for all therapeutic products have declined, total annual expenditures for direct mail approach 40 million dollars and the top ten pharmaceutical companies yearly spend over 18 million dollars.[20] Competing for this business are several companies some of which specialize in direct mailing in health care.[21] These companies rely on computer-stored lists which contain such specifics as type of practice, year started practice, specialization brands used, and attitudes toward certain aspects of medical practice. Although apparently more expensive per reader than journal advertising, the direct mailing companies claim that they reach a more select audience.[22] One direct mailing company claims that 43 percent of the people who receive its mail read it.[23] A typical mailing by a pharmaceutical company, according to Advertising Age, may each cost 35 cents and some companies annually send out 12 to 20 mailings of 35,000 to 40,000 pieces.[24]

Perhaps the most important factor in disseminating drug information to doctors is the detailer system. The largest portion, almost 70 percent, of the pharmaceutical industry's promotional budget is devoted to detailers.[25] These company sales representatives provide product information to physicians, pharmacists, and other health professionals.[26] Moreover, according to audit estimates the total amount spent on detailing activities increased 36 percent in the last four years.[27] In 1976, for example, drug companies spent $51 million to detail antibiotics, $27 million for tranquilizers, $24 million for antiarthritic drugs and $20 million for non-narcotic analgesics.[28] In 1977, an estimated 24,000 detailers provided approximately 200,000 physicians with various sorts of written and verbal information about several

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20 Chew, "Medical Mailers Seek Way Out of Doldrums." Advertising Age, Feb. 13, 1978, at 73.

21 Id.

22 Id.

23 Id. at 74.

24 Id.

25 Supra note 16.

26 Id.

27 Advertising Age, Feb. 13, 1978, at 68.

28 Id. at 70.

thousand drug products.[29] Detailers come from mixed educational backgrounds and, according to Advertising Age, as a group are not highly paid.[30] Most major drug companies have internal training programs designed to equip the detailer with technical information.[31] Besides working with doctors, detailers organize seminars and exhibits for hospital and medical school personnel. They also forward doctors' complaints about drug efficacy, complications, and interactions.

The well-funded and far-flung detailer system affects most doctors' prescribing decisions. For example, the AMA survey Opinions of AMA Members 1973 found that detailers have a "moderate" or "marked" influence on the prescribing habits of 50 percent of the doctors in its sample.[32] Similarly, physicians' mail or detailers were found to be the first sources of information about a new drug for 74 percent of all physicians.[33] Neither is there any dispute that detailers recommend only brand-name products and seldom provide price information. Drug companies' promotional expenses are aimed at maximizing the use of brand-name products.[34] And an industry spokesman candidly stated:

> [W]hat the detailman does is seek to persuade the doctor that when he writes a script he should write it for the detailman's product in preference to another product. Indeed, that is his job.[35]

Undoubtedly, the large expenditures devoted to detailing and other promotion by drug manufacturers produce a system in which practicing physicians are most familiar with drugs by their brand names.

Finally, a limited albeit potentially important source of prescription drug information to physicians is the pharmacist.

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29 Id. at 67.

30 Id. at 68.

31 See, e.g., PMA, "Guidelines for Programs of Technical Education for Training for Pharmaceutical Representatives," Oct. 16, 1975.

32 "In Whose Hands?," supra note 18, at 28.

33 Advertising Age, supra note 20, at 68.

34 Willig, "The Prosubstitution Trend in Modern Pharmacy Law," 6 U. Mich. J.L. Reform 1,16 (1972).

35 Furland, Chairman PMA, Pres., Squibb Corp. "The Pharmaceutical Industry faces the Future," Address, Apr. 3, 1974, at 7.

Although some doctors find the pharmacist to be a reliable source of prescription price information, most doctors seldom consult with pharmacists.[36] In a recent survey only 5.5 percent of the physicians and 5.7 percent of the pharmacists said that doctors consult with pharmacists "very often."[37] About 35 percent of the physicians and 39 percent of the pharmacists said "occasionally," while over one half of both groups characterized the rate of consultation as "seldom" or "never."[38]

C. The Role of Brand Names and Retail Prices in the Physician's Prescribing Decision

We turn now to quantitative evidence bearing on the influence these sources of drug information have on the physician's decision to prescribe by brand-name. As we have seen, the physician's formal pharmacological training usually does not include retail price information, and his continuing education relies predominantly upon brand-name information supplied by the pharmaceutical manufacturers. These facts indicate the limited role of retail prices and the large role of more convenient brand-names in most physicians' prescribing decisions.

Estimates vary, but the prevalence of prescribing by proprietary name is undisputed. The rate of brand name prescribing has soared from ten percent in 1909 and 42 percent in 1929 to about 90 percent in 1972.[39] Much of this meteoric rise may reflect the shift, described earlier, from drugs compounded by community pharmacists to the sophisticated brand-name products of the large drug makers. Nonetheless, it is commonly thought that the brand-name promotion described above together with unawareness of drug prices by physicians explain much of this phenomenon with respect to multisource drugs.[40] We will now

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36 Am. Druggist, November 1976, at 27.

37 20 Am. Med. News 5 (1977).

38 Id.

39 Compare, Richard G. Kedersha, "The Impact of Brand Name Prescription Drugs on the Traditional Practices of High Prescription Pharmacies in Northern New Jersey", 1964 (unpublished Ph.D. thesis, New York Univ.), at 64 with Am. Druggist, Feb. 1, 1974, at 44.

40 The summary and analysis of the hearings on Competitive Problems in the Drug Industry put it this way:

Firms which have acquired patent pro-

(Footnote Continued)

consider evidence demonstrating that drug product selection will make it easier for physicians more familiar with brand-names and preoccupied with their other medical duties to delegate product selection to pharmacists.[41]

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40 (Footnote Continued)

> tection . . . are free to promote the uses of the product without concern that other manufacturers will supply the same drug while the patent is in force. During this patent period, company sales representatives meet personally with prescribers to call attention to the drug. . . . The prescriber sees the product advertised widely in his professional journals. A variety of reminder advertisements and other materials are mailed to the practitioner and the detail man may visit the prescriber again and again to call attention to the company's new product. Each time the drug is discussed, it is identified by its trade-name, rather than by a generic name which identifies the active drug ingredients contained in the company's particular formulation.
>
> Over a period of time, physicians prescribing this product become familiar with its uses and limitations first-hand. . . . In any event, the practitioner becomes accustomed to thinking of, and ordering the drug by, its trade-name each time he finds it necessary to prescribe it for one of his patients. Before Subcomm. on Monopoly, Comm. on Small Business, U.S. Senate, 90th & 91st Cong., Nov. 2, 1972, at 7.

41 There is a much broader controversy over promotion in the drug industry which is not germane to the present discussion. The drug industry and its critics vehemently disagree, for example, on whether brand name promotion (1) causes overutilization of prescription drugs and (2) creates an irrational brand loyalty among physicians that hampers competition. The drug manufacturers maintain that detailing and other promotional efforts lead to better informed prescribing and that many promotional abuses are held in check by FDA regulations, the expertise of doctors, and the importance of reputation to both the detailer and his company. See PMA, "Purpose and Activities of Pharmaceutical Company Sales Representatives (Detailmen)," May 1974, at 3-4 and "How Physicians Rate Drug Companies," Product Management, at (Footnote Continued)

First, because physicians are busy people, many prescribe a brand name out of convenience; in effect the brand name becomes a shorthand version of the generic name. For example, twenty percent of 60 physicians surveyed in a Wisconsin study explained that their decision whether to prescribe by brand or generic name was due to convenience or habit.[42] Similarly, a PMA Committee re-

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41 (Footnote Continued)

30 (April, 1974). The PMA contends that although detailers are an important source of information, they have little effect in the physician's final decision to prescribe a particular drug. Advertising Age, supra note 20, at 7; "Purpose and Activities," supra, at 4-7.

Numerous drug industry critics, on the other hand, lament that this predominant source of doctors' drug product information is not provided by more disinterested parties. "In Whose Hands," supra note 18, at 28. Pointing to evidence of high profits for the drug industry, critics believe that these large sums spent on detailing grossly distort physician's prescribing habits. They also point to attempts by detailers to circumvent FDA warnings. One often cited example involved the National Research Council's recommendation that the chloramphenicol label warn that the drug "not be used indiscriminately or for minor infections" because a potentially fatal blood disease had occasionally been found to occur with its use. Parke Davis distributed a letter telling its detailers of the new warning label while insisting that the FDA and National Research Council had officially cleared the product with no restrictions. The letter appears to directly contradict the spirit if not the letter of the NRC's recommendation. Burack, The New Handbook of Prescription Drugs 15-16 (1976).

Neither drug product overutilization nor irrational brand loyalty among doctors, however, need be addressed here because neither issue is directly relevant to the generic substitution debate. The repeal of antisubstitution laws will not affect the physician's prerogative to decide when to prescribe nor can it override the physician's judgment to require that prescriptions be filled with a specific brand. Drug product selection laws need not alter either the flow or the reliability of the information disseminated by detailers. They will make it more convenient for physicians who customarily prescribe by brand name to delegate product selection authority to pharmacists.

42 Hammond & McCormick, "Some Economic Considerations in Generic and Brand Prescribing," 5 Med. Marketing & Media 14 (1970).

port found that except for old products that have lost or never had a brand image, convenience and habit are very strong secondary reasons for prescribing brands.[43] Furthermore, individual physicians have noted the important role convenience plays. Dr. Michael Halberstam, author of several books and articles, and nationally syndicated columnist on health, admitted, "Sometimes I prescribe by brand name because I don't remember the generic name."[44] Indeed, Dr. Halberstam supported drug product selection laws in part, because he believed they could "obviate the problem of physicians forgetting the generic name."[45] (For a discussion of why generic drug manufacturers do not actively promote to physicians and for examples of how cumbersome generic names can be see Chapter II. D., supra).

Second, many doctors place a low priority on price when writing prescriptions. It is well established that most doctors are not familiar with specific drug prices. Although some doctors are aware that unbranded products are lower priced,[46] when it comes to specific drug prices the vast majority acknowledge their ignorance. In a Philadelphia County survey designed to measure physicians' knowledge of drug prices, over 32 percent of the respondents from a diversity of practices replied that they had no idea of drug prices of commonly prescribed drugs.[47] Moreover, on a scale of one to five, nearly two-thirds of the remaining respondents ranked their knowledge of drug prices in the two lowest categories.[48] The same study measured physicians' objective knowledge of drug prices. Less than a third of the responding physicians correctly estimated (to within 20 percent) the price of drugs commonly prescribed in their respective specialties.[49] Furthermore, two and a half times as many incorrect answers

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43 PMA, Preliminary Report on the Effect of the Repeal of Antisubstitution Laws, Apr. 25, 1977.

44 "Generic Drugs," The MacNeil/Lehrer Report, Apr. 28, 1977, at 5.

45 Id. at 7.

46 Jerome Brown Communication Inc., "Antisubstitution Attitudes Among Physicians" (undated), at Question 1.

47 Fink & Kerringan, "Physician's Knowledge of Drug Prices," 1 Contemp. Pharm. Prac. 18, 19 (Summer 1978).

48 Id.

49 Id.

underestimated the price as overstated the price.[50] Using a similar technqiue, an earlier study of physicians in Palo Alto, California attempted to measure doctors' knowledge of prices. While a clear majority of the physicians indicated that they considered drug costs when prescribing, only a third could estimate the drug price to within 20 percent.[51] Finally, another survey found that neither physicians nor pharmacists believed that most doctors knew retail drug prices. Eighty-four percent of the pharmacists and 62 percent of the physicians said most physicians do not know the cost to the patient for drugs they commonly prescribe.[52]

This evidence that doctors lack knowledge of specific prices does not establish that they should spend more of their valuable time learning drug prices. Indeed, to do so may be an inefficient use of their time. The advantage of drug product selection is that it facilitates physician delegation to pharmacists whose primary professional endeavor is product selection. In any event, physician unawareness of drug prices (as demonstrated by the wide price disparity among equivalent versions of the same drug) is strong evidence of the low priority placed on drug prices. (For further discussion see Chapter VIII., infra). Differences are even found in the prices of drugs made exclusively by one firm but marketed by several firms under different names. The New York State Assembly's Office of Legislative Oversight and Analysis has documented cases in which generic manufacturers sell products both to a trade name house and to a wholesale distributor. For example, Barr Laboratories manufactures chlordiazepoxide hydrochloride and sells it to both Lederle Laboratories, for resale as a branded generic, and to Darby Drug Company, for resale as an unbranded generic. At wholesale, Lederle sells its product for $17.01 per bottle and Darby sells its product for $4.85 per bottle.[53] Assuming a comparable difference in retail prices, the patients of doctors prescribing the Lederle brand are paying a premium price for a product identical to Darby's.

Another indirect measure of the low priority physicians give

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50 Id.

51 Lowy, et al., "A Survey of Physicians' Knowledge of Drug Costs," 47 J. Med. Educ. 349, 350 (1972). This study compares the responses of physicians from academic and private settings. We need not concern ourselves with these distinctions.

52 Supra note 37.

53 Callahan, Fensterer, Langdon & Haddad, Report on Branded Generics, The Assembly State of New York, February 1978, at 167. For other examples, see Ch. II.D., supra.

CHAPTER X. THE FEDERAL TRADE COMMISSION'S ROLE

A. Model Drug Product Selection Act

Measurements of the potential benefits from drug product selection (Chapter VIII, supra) demonstrate that antisubstitution laws and regulations cost consumers hundreds of millions of dollars each year by restricting price competition in the multisource prescription drug market. And an analysis of the alleged disadvantages of drug product selection (Chapter IX, supra) demonstrates that consumer benefits can be achieved through enactment of appropriate product selection laws without compromising the quality of health care.

We recommend that the Commission offer states its assistance to facilitate pharmacists' selection of lower-cost generic equivalents whenever appropriate by encouraging states to adopt the FTC-FDA jointly-endorsed Model Drug Product Selection Act, discussed below.

We make this recommendation instead of other possible recommendations for several reasons. The states have been actively replacing their antisubstitution laws with drug product selection laws. The number of state product selection laws has more than doubled during the course of our investigation, leaving only ten states with restrictive antisubstitution laws.[1] In addition, a number of states are amending their product selection laws to make them more effective. In view of this activity, we think the most appropriate use of Commission resources is to assist states in their attempts to make product selection work.

The often-cited comment of Justice Brandeis about the value of the federal system in permitting states to serve as "laboratories" for "social and economic experiments"[2] is applicable here. We have tried in this report to analyze available evidence and identify those provisions of product selection laws that work best. In doing so, we also have tried to identify those areas in which the available evidence is not conclusive. Thus, there still seems to be justification for some experimentation by the states. We do not suggest that any state whose law is working well to produce substantial consumer savings make major modifications merely to conform to the Model Act. We do think, however, that a state law that follows the principles of the Model Act will work to save consumers money and to serve the public interest.

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1 See Table 1. State Laws, Ch. VII.B., supra.

2 New State Ice Co. v. Liebmann, 285 US. 262, 280, 311 (1932) (dissenting opinion).

Because both the FDA and the FTC are committed to facilitating drug product selection, we look forward to a resolution of this problem. We support the direction manifested by the FDA's new policy and proposed exemption for ads directed to consumers.[12] We encourage retailers to continue experimenting with advertisements designed to help consumers make informed decisions about generic drug products.

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12 The FDA and the FTC share jurisdiction over prescription drug advertising. Current food and drug law exempts the advertising of safety and efficacy information about particular drug products only from the coverage of §§ 12-17 of the Federal Trade Commission Act, sections which prohibit "false" advertising of prescription drug products. Federal Food, Drug and Cosmetic Act § 502, 21 U.S.C. § 352 (1970 & West Supp. 1977).

In 1971 the two agencies agreed to an allocation of responsibilities in regulating the advertising of food, drugs, devices and cosmetics. This allocation reflected FDA's primary responsibility to regulate the truth or falsity of prescription drug advertising, 3 Trade Reg. Rep. (CCH) ¶ 9851 (1971).

The proposed Drug Regulation Reform Act of 1978 as introduced in the last session of Congress would preserve this jurisdictional relationship. Hence, the Commission's jurisdiction over "deceptive and unfair" acts and practices in the advertising of prescription drugs in general remains intact. Federal Trade Commission Act § 5, 15 U.S.C. § 45 (1970 & Supp. V 1975).

CHAPTER XI. OTHER REMEDIAL APPROACHES

We believe that effective drug product selection laws will work to stimulate price competition in the multisource prescription drug market. A detailed analysis of alternatives to drug product selection is outside the scope of this report; however, in this section we briefly list some of the proposals most frequently suggested.

Critics of the pharmaceutical industry have proposed patent reform, principally compulsory licensing, for years. Proponents maintain that compulsory licensing, by enabling licensees to sell products still on patent, would dilute or erode the market power innovator firms establish through patent protection in conjunction with trademark registration and cross-licensing agreements.[1] At least 25 western countries[2] provide for compulsory licensing on various grounds,[3] including an adverse effect on public health or safety from the failure to license[4] or excessive market concentration from ownership of an entire group of patents.[5]

In this country, compulsory licensing has emerged primarily

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1 See, e.g., Steele, "Patent Restrictions and Price Competition in the Ethical Drugs Industry," 12 J. Indus. Econ. 198 (1967). See also, Jadlow, "Competition and 'Quality' in the Drug Industry: The 1962 Kefauver-Harris Drug Admendments as Barriers to Entry," Antitrust L. & Econ. Rev., Winter 1971-72, at 103, 106. Steele "Monopoly & Competition in the Ethical Drugs Market," 5 J. Law & Econ. 131, 161 (1962).

2 France, for example, has such a provision. Forman, The Economics of Drug Innovation 180 (J. Cooper ed. 1969). According to some commentators, countries with compulsory licensing schemes rarely apply them. Whitney, "Economics of Ethical Drug Industry: A Reply to Critics," 13 Antitrust Bull. 803, 836 (1968).

3 For additional grounds, see Mirabito, "Compulsory Patent Licensing for the United States: A Current Proposal," 57 J. Pat. Off. Soc'y 404, 420 (1975).

4 Canada, France, and the United Kingdom have such a provision. Mirabito, supra note 3, at 424.

5 Forman, supra note 2, at 178. For detailed information about patent systems in other western countries, see Evanson & Wertheimer, "Patent Licensing of Pharmaceuticals," 7 Inquiry 60 (1970); Forman, supra note 2; Steele, 5 J. Law & Econ., supra note 1, at 135 n. 12.

TAB 2

GENERIC SUBSTITUTION AND PRESCRIPTION DRUG PRICES:

Economic Effects of State Drug Product Selection Laws

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1985

GENERIC SUBSTITUTION AND PRESCRIPTION DRUG PRICES:

ECONOMIC EFFECTS OF STATE DRUG PRODUCT SELECTION LAWS

by

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Federal Trade Commission

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CHAPTER 1

INTRODUCTION

As of mid-1984 all states have laws allowing pharmacists some choice in selecting which brand of drug to dispense in filling a prescription that names a specific brand.[1] The stated purpose of these drug product selection (DPS) laws is to lower the prices consumers pay for prescription drugs through substitution of lower-price versions of the drug for the higher-price brands typically prescribed by physicians.[2] The previous anti-substitution laws required the pharmacist to dispense whichever brand the physician named. The newer drug product selection laws under certain conditions allow the pharmacist to substitute another generically equivalent drug. Since most prescriptions are written using the proprietary name of a specific brand, rather than the established generic name of the drug product, DPS laws in effect shift the choice of brand for most prescriptions from the physician to the pharmacist. The premise underlying DPS laws is that the pharmacist has a greater incentive than the physician to identify the cheapest source of supply and to pass along at least part of the savings to the consumer.

It is the large price differences between leading brands and "generic" versions of the "same" drug that suggest that consumers could save substantially from substitution.[3] Using

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1/ By 1980 -- the year analyzed in this report -- only three states still prohibited substitution. Louisiana's law went into effect in October of 1980, Texas' at the beginnning of 1982 and Indiana's in mid-1984.

For a history of the anti-substitution laws and of their replacement with drug product selection laws see Staff Report to the Federal Trade Commission, Drug Product Selection, 1979, hereafter cited as FTC Staff Report (1979).

2/ "Generic substitution" is another term often used for drug product selection, and indeed the substitution of unbranded drug products for branded items is envisioned by the statutes in that lower-price products typically include those sold under the generic name only. The term "drug product selection" encompasses a broader range of pharmacist behavior. In filling generically written prescriptions, pharmacists must always choose a drug product. Also, a substitution may involve a second brand rather than a lower-price unbranded version.

The type of substitution analyzed in this study is limited to brand interchange within a generic entity (or drug entity), defined as the set of products which all have the same (combination of) active chemical ingredient(s).

3/ In this study, "generics" are defined as being all products other than leading brands, thereby including some products sold under a proprietary name in addition to products sold under the generic name alone. See Appendix A6 for the definitions of "leading brands" and "generics" and Chapter 3 for data on leading brand and generic prices.

measures of the brand-generic price gap, a number of previous studies have attempted to measure the potential savings which DPS laws offer. These estimates have been large, on the order of hundreds of millions of dollars per year.[4]

This study is an empirical analysis of the effects of these laws. We measure these effects in terms of substitution rates and differences in prices while controlling for influences other than the laws. While our primary data are for 1980, we also discuss more recent trends.

I. EQUIVALENCE AMONG DRUG PRODUCTS

Consumers benefit from substitution only if there is no significant offsetting diminution in therapeutic efficacy. One important prerequisite for the spread of drug product selection laws was the growing acceptance of the view that for many drugs various brands could be interchanged without loss of therapeutic efficacy.

The issue of *therapeutic* equivalence among *generically* equivalent products is real. Two same-strength products in the same generic entity, containing the same active chemical ingredients in identical proportions, may not always have the same effects in a patient, because differences in inactive ingredients used for binding or coloring may modify the effects of the active ingredients or create their own unintended side effects.

However, for many generic entities, there is now substantial agreement that no serious inequivalence problems exist,

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4/ See FTC Staff Report (1979), which reviews several estimates. These estimates all assume that dollar savings are not offset by a diminution in therapeutic efficacy. Most estimates are of the maximum potential benefits, that is, the savings that would occur if substitutions were in fact made in every instance permissible. Of course, the actual amount of "savings" depends on the extent to which pharmacists have the opportunity to substitute and on whether they actually choose to exercise the substitution option, as well as on any indirect price effects of the DPS laws.

based either on testing or on long experience.[5] For some others, tests have shown that products are not equivalent and that free interchange is not appropriate.

All state drug product selection laws prohibit substitution of products judged to be inequivalent, but they differ in the means by which they specify which products are considered to be equivalent. In some states reliance is placed entirely on independent judgment of the pharmacist, although a criterion typically using the terminology of bioequivalence or therapeutic equivalence may be incorporated in the statute. In many states (two-thirds of the states in 1980) a formulary lists permissible (or, alternatively, impermissible) drug product interchanges.[6] The formulary's legal grant of permission to substitute is for a particular drug entity very like the broad grant provided by the existence of a drug product selection statute: without it, substitution is illegal, regardless of how much encouragement other provisions of the law give to substitution in general. Data for all states permitting substitution in 1980 show that substitution was permitted on 73.6

5/ In a 1979 Federal Register notice, the FDA Commissioner was reported as being "convinced that only a small fraction of all drugs present bioequivalence problems, and that, among those drugs that are currently marketed by more than one supplier, the problem drugs have now mostly been identified." 44 Federal Register 2942, January 12, 1979. Two products are said to be bioequivalent if their absorption into the blood stream and their subsequent excretion into the urine occur at the same rate and to the same extent; in practice, bioequivalence is held to imply therapeutic equivalence. Under FDA regulations some but not all drugs have been tested for bioavailability. In fact, the lack of bioequivalence does not necessarily lead to a significant difference in therapeutic effect. According to the FTC Staff Report (1979, p. 241), "small differences in bioavailability were likely to produce therapeutic problems for drugs with either a steep dose-response curve or a narrow range separating effective and toxic levels. Most clinically useful drugs have relatively flat dose-response curves; therefore, only large differences in bioavailability were likely to alter their therapeutic effect." Members of the expert panel whose report was published by the Office of Technology Assessment in 1974 "estimated that roughly 85 percent to 90 percent of all prescription drugs were not critical dose drugs for which bioavailability studies were necessary." FTC Staff Report (1979, p. 238, footnote.)

6/ Formularies which list permissible substitutions are called "positive" formularies; those that list drugs in which substitution is prohibited are "negative" formularies. The effects of this difference are discussed in Chapter 5, as are secondary effects of formularies, such as limiting liability and simply providing information.

percent of all prescriptions for 45 leading multi-source drugs studied.[7]

State formularies vary greatly; the proportion of all prescriptions in these 45 drugs on which substitution was permitted in 1980 ranged from 29 to 98 percent.[8] This shows that there is no single, universally agreed upon list of drugs which should be considered interchangeable.[9] Since 1980 the Food and Drug Administration has published its judgments in a periodical list entitled Approved Prescription Drug Products with Therapeutic Equivalence Evaluations.[10] Many states use the FDA list as a basis for their own formularies or, in the absence of a state formulary, recommendations to practicing pharmacists. Without such a standard compilation of official opinion, drug product selection laws would have been much more difficult to implement.

For the purposes of this study, we use the therapeutic evaluations embodied in state formularies as the standard for determining when a substitution can be made with no loss in therapeutic effectiveness. We do, however, note the inconsistency of this standard across states for some drugs.

II. THE ECONOMIC RATIONALE FOR SUBSTITUTION LAWS

In "perfect" markets, consumers choosing between two identical products with different prices would choose the lower-price product, and the price differential could not be maintained. However, in many "real" markets, price differentials

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7/ The data and the selection of the 45-drug sample are described in section III below and in greater detail in Appendix A6.

8/ See Appendix Table A1-1 for 1980 data by state.

9/ General agreement on the advisability of prohibiting substitution in a particular drug entity is reflected in the fact that for some drugs substitution is permitted in all states while for others substitution is prohibited in most formulary states. Appendix Table A3-2 shows for each of the 45 drugs analyzed in this study the number of states which permitted substitution in that entity in 1980. The proportion of prescriptions on which substitution was permissible in 1980 (excluding the three states which prohibited all substitution) ranged from 55 to 100 percent across the 45 drugs.

10/ U.S. Department of Health and Human Services (1980 and subsequent editions).

persist, and in the market for prescription drugs the legal prohibitions against substitution have contributed especially to sustained price differentials.

The difference between the price of the leading brand in a prescription drug entity and the price of alternative brands in the same entity is typically large: a 1980 average across 37 leading multi-source drugs, weighted by sales in number of prescriptions, was $8.22 for the leading brand and $6.22 for the average of other brands, a difference of $2.00, or nearly 25 percent of the leading brand price.[11] Despite this broad price gap most prescriptions are filled with the leading brand. None of 12 leading drugs whose patents expired between 1970 and 1976 had in 1979 a market share of less than 90 percent in (wholesale) dollar terms, although market shares were lower (70 to 90 percent) in terms of units sold.[12] Market share erosion is moderate at best in the years following patent expiration.[13]

The institutions of the prescription drug market are markedly different from those in most other product markets. For prescription drugs, it has not been the consumer who has made the choice among brands; it has been the physician. A physician's prescription is a necessary precondition for the purchase of a prescription drug, and it is the physician who designates both the chemical compound and, on four-fifths of

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11/ Of the 45 drugs selected for study, in only 37 did sales of both brands and generics, by our definitions, actually appear in the 1980 data.

12/ The analysis of dollar market share is in Statman and Tyebjee (1981). The analysis of unit market share is contained in a letter from Mark B. Goodson, Associate Manager, Public Policy Planning, Hoffmann-La Roche Inc. to Robert L. Steiner, January 6, 1982. The computations were based on IMS data and covered 6 of the 12 drugs in the Statman/Tyebjee analysis. By mid-1981 the unit market shares had fallen to 58 to 84 percent in these drugs.

13/ Of course, one possible explanation of the persistence of the price differential is that leading brands are superior in quality. Despite official state formularies stating that certain brands are interchangeable, some consumers or their physicians may find that one brand is more effective or confers fewer side-effects than another. Even in the absence of laws or institutions restricting their options to purchase prescription drugs, some consumers would therefore be willing to pay a premium for certain brands of powerful drugs, just as they do now for over-the-counter drugs and other products.

all prescriptions, a specific brand of the drug.[14] In the absence of the opportunity to substitute, consumers have no opportunity to exercise an unfettered choice of brand on most of the prescriptions received.

Physicians' behavior reveals not only a marked preference for prescribing brand-name drugs but also for specifying the first brand marketed in a drug entity.[15] In the absence of substitution, this proclivity towards prescribing the pioneer brand in effect extends the drug's dominance even after the expiration of the patent which conferred the initial legal monopoly. One explanation of this pattern is that physicians' prescribing habits are formed early in the life of a newly-introduced drug, at a time when there is only one version of the drug, protected by a patent monopoly and promoted heavily by its manufacturer. These habits are resistant to change, even in the face of the lower prices set by post-patent competitors of the leading brand.

Of course it is possible that physicians' preferences for brands accurately reflect consumers' preferences, but there are strong arguments to the contrary. First, there is evidence that physicians are poorly informed about relative prices of drugs.[16] Second, physicians' incentives to choose the most cost-effective drug seem weak. A patient buys a bundle of services from the physician and may consider the particular brand of the drug to be a minor aspect in choice of a physician, giving much greater importance to diagnostic ability and overall quality of care. Moreover, to the extent that choice of physician is influenced by the cost of the physician's services, the variability in other components of that total cost -- such as the cost of the consultation itself and the cost of laboratory tests -- may swamp differences in prescription costs. Finally, patients themselves are not knowledgeable about the availability and relative prices of different brands within a generic entity and therefore may not

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14/ In 1980, 79.9 percent of multi-source prescriptions specified a brand. This figures is a weighted average for 45 multi-source drugs.

The remaining 20.1 percent were written generically. Regardless of whether the law permits substitution on brand-written prescriptions, selection of a particular product is necessarily left to the pharmacist and the consumer when the prescription has been written by generic name only.

15/ Bond and Lean (1977).

16/ See discussion and references in FTC Staff Report (1979, pp. 64-67).

notice when the physician's prescription is not the best alternative available.[17]

Since physicians are an unlikely force behind a switch to lower-cost brands after the patent period has expired, an erosion of the patent-conferred monopoly must depend on others who have both the power and the incentive to respond to lower prices. That is the role envisioned for the drug product selection laws: to transfer some of this power to pharmacists.[18] Consumers are the ones most interested in a lower price, and pharmacists must respond to consumer demand because of direct competition with other pharmacies on prescription prices. Also, pharmacists have an immediate incentive to dispense a generic rather than a leading brand because typically the retail dollar gross margin on the generic is higher.[19] Anti-substitution laws, then, prevented pharmacists from dispensing the highest-profit products, and DPS laws can be viewed as the removal of a constraint on pharmacists' choices. Under the DPS laws, the profit-seeking drug retailer is more likely to choose a drug product with a lower (wholesale) cost and to sell it to consumers at a price below that of the leading brand. By making use of the pharmacist's interest in higher profits, DPS laws offer consumers the benefit of lower prices.

III. DATA USED IN THIS STUDY

Our primary data are from the National Prescription Audit (NPA) compiled by IMS America, Ltd. and are for 1980; we also make use of some more recent data from various sources. In the

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17/ See Chapter 3.

18/ Under all state DPS laws, the physician retains the authority explicitly to prohibit substitution on a particular prescription. In almost all states consumers also have the right to refuse substitution.

19/ See Chapter 3. Also, on publicly funded prescription drug programs, such as Medicaid, pharmacies may by the regulations be given an incentive dispense low-cost versions, as is done with the Maximum Allowable Cost (MAC) program which sets reimbursement ceilings for some drugs. Private insurers now also build into their reimbursement schedules incentives for generic dispensing.

1980 NPA, over a million individual retail prescription transactions were recorded from a panel of about 800 retail pharmacies in 48 states and the District of Columbia. For each prescription we have information on the drug product prescribed and the drug product dispensed, and the retail price. We cannot tell, however, whether the physician prohibited substitution. Some data from IMS' 1980 U.S. Drugstore Audit, on drug invoice costs at the pharmacy level, are also used.

From the 1980 data we selected 45 multi-source entities, the definition of a generic entity setting the broadest boundary within which substitution may be permitted.[20] The number of brands within an entity ranged from 2 to over 100. These 45 entities constituted nearly all the multi-source drug entities that appeared among the top 100 entities ranked by dollar sales to drugstores. Of these 45, only 37 turned out to have observations in our sample for both the leading brand and at least one generic. When brand-generic comparisons are made, these 37 drugs are used rather than the entire 45. In addition to cross-tabulations, we used multivariate regressions (generalized least squares for the price analyses and logit for the brand choice analyses) to separate out effects of individual provisions of the laws and to hold constant other economic influences.

IV. RESULTS OF THE STUDY

The aim of the drug product selection laws was to reduce the prices consumers pay at retail for their prescription drugs by shifting some market share from higher-price leading brands to lower-price versions of the drug, and this aim was accomplished. Substitutions are made and average prescription prices do fall. The magnitude of the accomplishment, however, was smaller than might have been anticipated, even when the upsurge in the last few years is taken into account.

20/ Dosage form and strength must also be identical. In some generic entities in some states, substitution is permissible only for selected dosage forms.

Like others before us, we find that substitution has been infrequent. Overall, in 1980 substitution occurred on about 5.5 percent of prescriptions written for a specific brand for which an alternative product was available.[21] When prescriptions for which substitution was legally proscribed are removed, this rate rises to 7.3 percent. Even if approximate adjustments are made for the fact that physicians sometimes prohibit substitution explicitly, the overall substitution rate could not have been higher than 10 percent of all prescriptions eligible for substitution in 1980.[22]

Substitution has been increasing and it is predicted to increase even more. The substitution rate in 1984 was double that in 1980, occurring still on probably less than a fifth of all eligible prescriptions.[23] Consumers, pharmacists, and physicians have presumably been gaining experience and knowledge about both the opportunities for substitution and its desirability. Moreover, the Hatch/Waxman Act of 1984, which makes less costly the introduction of generic products after the expiration of the patent of a leading brand, is expected to evoke a significant increase in the number of generic products on the market. Our overall measures of 1980 behavior, then, are an understatement of the role of substitution in 1985 and beyond.

Even in 1984, however, substitution was relatively infrequent. This is puzzling in light of the incentives both consumers and pharmacists have to substitute. The most likely explanation is lack of clear and accurate information. In particular, it may be that consumers and pharmacists read into the fact that physicians specify a brand a strong preference on the physician's part for that particular brand, even when the physician does not choose to exercise the legal option to prohibit substitution explicitly. The physician may not, in fact, have that strong a preference, but the consumer's or pharmacist's uncertainty deters acceptance of a substitute brand.

21/ Nearly all (95 percent) substitutions were from leading brands to generics.

22/ See Chapter 2.

23/ See Chapter 2.

There are many sources of variation in the frequency of substitution. Substitution rates are very different from drug to drug, from none at all to a maximum, in 1980, of over 20 percent. Substitution was most common for Medicaid consumers and least common for privately insured consumers, with uninsured consumers intermediate. We tested the hypothesis that chain drugstores are more likely to substitute than independents but found that the data did not support it. The extent of substitution varies also from state to state.

One possible source of variation is the specific content of the state laws. Each DPS law is a composite of individual provisions, specifying the design of the physician's prescription pad (making it convenient or inconvenient for the physician to prohibit substitution), stating whether or not cost savings due to substitution must be passed through to the consumer, and regulating other aspects of the substitution process. In 1979 the FTC and the FDA together recommended to the states adoption of a set of specific provisions believed to promote drug product selection most effectively. The FTC/FDA Model Drug Product Selection Act is reproduced in full in Appendix A2.[24]

Some of the individual provisions of the state laws are shown to make a significant difference in the incidence of substitution. The contents of formularies, which prohibit substitution on certain drugs, of course have a substantial impact on overall substitution. Given that substitution is permitted, however, the presence of a (positive) formulary, appears to diminish substitution. The design of the physician's prescription pad is shown to be very important, confirming earlier findings and validating the recommendation of the Model Act. In particular, if prohibition of substitution is made especially convenient for the physician, substitution occurs less frequently because, presumably, physicians prohibit it more often. States which require pharmacists to discuss substitutions with customers have higher rates of substitution, suggesting that where consumers' attention is drawn to the

24/ The Commission's recommendations were based in part on the FTC Staff Report (1979).